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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/835,537	04/16/2001	Carl R. Merrill	PNC-004	5407

7590 10/21/2004

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EXAMINER

PRYOR, ALTON NATHANIEL

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 10/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/835,537

Applicant(s)

MERRIL ET AL.

Examiner

Alton N. Pryor

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 13 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-4, 7-10, 13-14, 19-21, 23, 24 and 27-29 is/are rejected.
- 7) ☐ Claim(s) 5, 6, 11, 12, 16-18, 22, 25, 26 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

### DETAILED ACTION

Applicant's arguments filed 7/13/04 have been fully considered but they are not persuasive. See arguments below.

I. Rejection of claims 1,2,7,9,10,15,19,20,23,24 under 35 USC 102(b) as being anticipated by Pocchairi will be maintained for reason on record and reason as follows.

Applicant argues that nowhere in Pocchairi is describe the use of urea for treating prion disease (scrapie). Examiner disagrees with Applicant and maintains that Pocchairi administers urea to treat scrapie (prion disease).

II. Rejection of claims 1-3,9,10,13-15,19-21,23,24,27-29 under 35 USC 102(b) as being anticipated by Manuelidis for reason record and reason as follows. Applicant argues that Manuelidis method of treating scrapie and CJD with guanidine HCl is shown in vitro studies rather than in vivo (administering the guanidine HCl to mammals).

Examiner disagrees with Applicant. Examiner argues that Manuelidis does not appear to be limited to in vitro studies.

III. Rejection of claims 1,2,9,10,15,19,20,23,24 under 35 USC 102(b) as anticipated by Goldin will be maintained for reason on record and reason as follows. Applicant argues that Goldin teaches treating insomnia with guanidine salt. However, Applicant argues that insomnia is not a prion disease. Examiner argues that insomnia is listed as a prion disease in claim 9 line 4.

IV. Rejection of claims 1,2,7-15,19,20,22-29 as being anticipated by Madec will not be maintained. Examiner argues that Madec is limited to in vitro studies and does not teach in vivo studies.

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V. Rejections of claims under 35 USC 102 as being anticipated by Chang or Garssen will not be maintained. Applicant is correct in that the reference do not disclose the administration of a prion agent to a mammal to treat a prion disease. Garssen's and Chang's rejections under 35 USC 103(a) will be dropped for the same reason.

VI. Rejection of claim 8 under 35 USC 103(a) as being obvious over Pocchairi will be maintained for reason on record and reason as follows. See I above.

VII. Rejection of claim 4 under 35 USC 103(a) as being obvious over Manuelidis will be maintained for reason on record and reason as follows. See II above.

VIII. Claims 5,6,11,12,16-18,22,25,26 are objected to for reason on record.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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***Telephonic Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alton N. Pryor whose telephone number is 571-272-0621. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Alton N. Pryor', is written over a horizontal line.

Alton Pryor  
Primary Examiner  
AU 1616